

**REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

**I. CLAIM STATUS AND AMENDMENT**

Claims 1-10 were pending in this application when last examined.

Claims 1-10 were examined on the merits and stand rejected.

Claims 3, 6 and 8 are cancelled herein without prejudice or disclaimer thereto.

Claims 1 and 4 are amended herein to clarify the claimed invention. Support for these amendments may be found in the claims as originally filed and in the specification in paragraphs [0009], [0011], [0020] and [0022].

No new matter has been added.

**II. FOREIGN PRIORITY CLAIM**

Applicants respectfully note that on page 1 of the Office Action, the Examiner did not acknowledge the claim for Foreign Priority. Applicants respectfully request that the Examiner check the file and acknowledge this claim in the next Office Action.

**III. NOVELTY REJECTION**

On page 2 of the Office Action, claims 1-2, 4-5 and 8 remain rejected under 35 USC 102(b) as anticipated by Simon et al.

Applicants respectfully traverse this rejection as applied to the amended claims.

Applicants note that claim 1 is amended herein to incorporate subject matter of non-rejected claim 6, in addition to subject matter from claim 8.

Applicants further note that the sequence order is different from the Simon et al. reference. Applicants' response of December 8, 2009, stated the following: "In contrast, according to the process of Simon et al., CMP-NeuAc is purified by use of NH4OH, ethanol, etc., followed by the addition of phosphatase and MgC12, and then the addition of ethanol (the second addition). Applicants respectfully assert that this passage clearly indicates that the sequence order of addition in the claimed invention differs from the Simon et al. reference.

Thus, claim 1, as amended herein, incorporates subject matter from a non-rejected claim; further, the sequence of addition differs between the claimed invention and the cited reference.

For these reasons, Applicants respectfully submit that the claims, as amended herein, are not anticipated by the cited reference. Therefore, Applicants respectfully submit that the rejection is untenable as applied to the amended claims and should be withdrawn.

#### **IV. OBVIOUSNESS REJECTION**

Claims 1-10 are rejected under 35 USC 103(a) as being unpatentable over Simon et al. in view of Warren et al. and Vann et al. Applicants respectfully traverse this rejection as applied to the amended claims.

The essential feature of the claimed invention resides in the combination of the following items (A) to (G):

- (A) There is employed a solution containing CMP-NeuAc synthesized from cytidine 5'-triphosphate (5'-CTP) and neuraminic acid (NeuAc), which serve as substrates, and CMP-NeuAc synthase, which serves as a catalyst.
- (B) Steps (1) to (4) are performed in either the sequence of step (1) → step (2) → step (3) → step (4), or in the sequence of steps (1) and (2) being performed simultaneously → step (3) → step (4).
- (C) Step (1): adding a calcium ion or a manganese ion to a CMP-NeuAc-containing solution, thereby causing phosphoric acid, pyrophosphoric acid, and a nucleotide which coexist with CMP-NeuAc to precipitate.
- (D) Step (2), adding a phosphatase to the CMP-NeuAc-containing solution, thereby converting the nucleotide which coexists with CMP-NeuAc into a nucleoside.
- (E) Step (3): adding an alcohol having a carbon number of 5 or fewer, thereby precipitating CMP-NeuAc.
- (F) Step (4): collecting the thus-precipitated CMP-NeuAc.
- (G) Through the above (A) to (F), CMP-NeuAc having an HPLC purity of 95% or higher is obtained without performing any chromatography treatment.

That is, the meritorious effect of the claimed invention is that CMP-NeuAc having a purity of 95% or higher as determined by HPLC—which previously was only obtainable by

performing an intricate purification process of chromatography treatment--can be obtained from the combination of the above (A) to (G) at high yield.

Simon et al., which is discussed in paragraph [0006] of the present specification as Non-Patent Document No. 1, discloses: From a CMP-NeuAc-containing solution that has completed reaction, nucleotide is removed through CTP precipitation (which is performed through addition of ethanol and ammonia water) and hydrolysis (by alkaline phosphatase). Subsequently, through addition of ethanol and ammonia water, CMP-NeuAc is precipitated and recovered. The purity of the thus-obtained CMP-NeuAc was found to be lower than 90%.

Thus, even when the steps (2), (3) and (4) of the claimed invention are performed, the purity of the resultant CMP-NeuAc cannot reach 90%.

In contrast, the claimed invention, in which steps (1) to (4) are performed in a specifically determined sequence, can attain an HPLC purity of 95% or more without using a chromatography treatment.

It follows that one skilled in the art, such as Simon, would not expect that the simple precipitation method of the claimed invention could produce CMP-NeuAc that is 95% or more pure, without the use of purification steps such as chromatography, etc. Thus, the purity results (95% or more) obtained by the claimed invention would be unexpectedly high to one skilled in the art.

For these reasons, Applicants respectfully submit that one of skill in the pertinent art would find no reason in the teachings of the cited references to combine or modify their teachings in order to arrive at the claimed invention, nor would he have any reasonable expectation of success in doing so.

**CONCLUSION**

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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